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Registration Decision RD2013-08

Tetraconazole Technical Fungicide

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Registration Decision for Tetraconazole Technical Fungicide

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Tetraconazole Technical Fungicide and Mettle 125 ME Fungicide containing the technical grade active ingredient tetraconazole to control powdery mildew on grape, gooseberry, strawberry and sugar beet; black rot on grape; and cercospora leaf spot on sugar beet.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2012-29, *Tetraconazole Technical Fungicide*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for tetraconazole and summarizes the Agency's decision, the reasons for it. The PMRA received no comments on PRD2012-29, *Tetraconazole Technical Fungicide*. This decision is consistent with the proposed registration decision stated in PRD2012-29, *Tetraconazole Technical Fungicide*.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2012-29, *Tetraconazole Technical Fungicide* that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act*"...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Tetraconazole Technical Fungicide?

Tetraconazole is a broad-spectrum triazole fungicide belonging to the DMI (DeMethylation Inhibitors) group. It inhibits the metabolic pathway that leads to fungal sterol production, which makes fungal cell membranes nonfunctional. Tetraconazole is a systemic fungicide and is absorbed quickly into the plant tissue. It has protectant and curative properties.

Health Considerations

Can Approved Uses of Tetraconazole Technical Fungicide Affect Human Health?

Mettle 125 ME Fungicide containing Tetraconazole Technical Fungicide is unlikely to affect your health when used according to label directions.

Potential exposure to Tetraconazole Technical Fungicide may occur through the diet (food and water), when handling and applying the end-use product Mettle 125 ME Fungicide or when entering treated sites. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when pesticide-containing products are used according tolabel directions.

In laboratory animals, Tetraconazole Technical Fungicide was of slight acute toxicity via the oral route and low acute toxicity via the dermal and inhalation routes of exposure; consequently, the hazard signal words "CAUTION – POISON" are required on the label. It was minimally irritating to the eyes, non-irritating to the skin, and did not cause an allergic skin reaction. The acute toxicity of the end-use product Mettle 125 ME Fungicide was low via the oral, dermal and inhalation routes of exposure. It was minimally irritating to the skin and eyes and did not cause an allergic skin reaction. Consequently, no hazard signal words are required on the label.

There was no indication that Tetraconazole Technical Fungicide caused damage to the nervous system or immune system. There was also no evidence to suggest that it damaged genetic material or caused birth defects in animals. In addition, the young do not appear to be more sensitive to Tetraconazole Technical Fungicide than the adult animal. Health effects in animals given repeated doses of Tetraconazole Technical Fungicide included effects on the skin at points of contact, bones, liver, kidneys, ovaries, adrenal glands and thyroid gland, as well as irritation of the upper respiratory mucosal membranes. Tetraconazole Technical Fungicide also caused liver tumours in the mouse. When Tetraconazole Technical Fungicide was given to pregnant or nursing animals, fertility was slightly reduced and effects on the skeleton, liver, kidneys and body weight of the developing fetus were observed. These effects, as well as slightly delayed maturation in the juvenile animal, were observed at doses that were toxic to the mother.

The risk assessment protects against the effects of Tetraconazole Technical Fungicide by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Residues in Water and Food

Dietary risks from food and water are not of concern

Aggregate dietary intake estimates (food plus water) revealed that the general population and infants less than one year old, the subpopulation which would ingest the most tetraconazole relative to body weight, are expected to be exposed to less than 48% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from tetraconazole is not of concern for all population sub-groups. There were no cancer risks of concern for tetraconazole.

An aggregate (food and water) dietary intake estimate for the highest exposed population (one- to two-year-old children) used less than 2% of the acute reference dose, which is not a health concern.

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit. Pesticide maximum residue limits are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act.* Food containing a pesticide residue that does not exceed the established maximum residue limit does not pose an unacceptable health risk.

Residue trials conducted throughout the United States using tetraconazole on sugar beets, strawberries and grapes were acceptable. The maximum residue limits for this active ingredient can be found in the Science Evaluation of this consultation document.

Risks in Residential and Other Non-Occupational Environments

Occupational Risks From Handling Mettle 125 ME Fungicide

Occupational risks are not of concern when Mettle 125 ME Fungicide is used according to the proposed label directions, which include protective measures.

Farmers and custom applicators who mix, load or apply Mettle 125 ME Fungicide, as well as field workers re-entering freshly treated fields, can come in direct contact with tetraconazole residues on the skin. Therefore, the label specifies that anyone mixing/loading and applying Mettle 125 ME Fungicide must wear a long-sleeved shirt, long pants, chemical resistant gloves, socks and footwear during mixing and loading, application, clean-up and repair. The label also requires that workers do not enter treated fields for 12 hours after application. Taking into consideration these label statements, the number of applications and the expectation of the exposure period for handlers and workers, the risk to these individuals are not a concern.

For bystanders, exposure is expected to be much less than that for workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Tetraconazole Is Introduced Into the Environment?

Tetraconazole enters the environment when used as a foliar treatment on field crops. Once in the terrestrial environment, tetraconazole binds to soil particles and has limited vertical movement in most soils profiles. Tetraconazole is very persistent in soil; therefore, it is expected to carryover from one growing season to the next and, over a long period of time, has potential for reaching groundwater. In aquatic systems, tetraconazole is expected to move from the water column into sediments where it will persist. Tetraconazole is rapidly metabolised and excreted in fish and is therefore not expected to bioconcentrate. Tetraconazole is not expected to evaporate from the soil or water surface; therefore, the atmospheric concentration of tetraconazole is expected to be negligible. Tetraconazole is not expected to form any major transformation products in the environment because the transformation products transform much more quickly than they are formed.

Mettle 125 ME Fungicide is to be applied by field boom and airblast sprayers. Non-target terrestrial and aquatic habitats can potentially be exposed to tetraconazole as a result of spray drift or runoff. When used according to the label directions, tetraconazole does not present a risk to earthworms, bees, and aquatic organisms. Tetraconazole application can present a risk to beneficial predatory arthropods, terrestrial plants, birds and small mammals; therefore, label statements are required on the product label to inform users of the potential risks. No-spray buffer zones are required between the treated area and downwind terrestrial habitats in order to minimize the potential risk to terrestrial plants from exposure to off-field drift.

Value Considerations

What Is the Value of Mettle 125 ME Fungicide?

Mettle 125 ME Fungicide, containing Tetraconazole Technical Fungicide, has demonstrated effectiveness in controlling powdery mildew on grape, gooseberry, strawberry and sugar beet; black rot on grape; and cercospora leaf spot on sugar beet. Mettle 125 ME Fungicide is formulated in micro emulsion and applied as a foliar treatment. Mettle 125 ME Fungicide adds an alternative to the triazoles fungicides which will contribute to the limited disease management options for these targeted diseases. In addition, registration of this product will give Canadian growers access to an effective fungicide that is already available in the United States.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of Mettle 125 ME Fungicide to address the potential risks identified in this assessment are as follows:

Key Risk-Reduction Measures

Environment

Tetraconazole can pose a risk to certain beneficial insects, terrestrial plants, birds and small mammals. Precautionary label statements informing users of the risks to these organisms are required on the product label. Spray drift of tetraconazole may pose a risk to non-target terrestrial vascular plants. To mitigate potential exposure via spray drift, a no-spray buffer zone of one metre is required to protect sensitive terrestrial habitats downwind. An advisory statement recommending products containing tetraconazole not be applied in areas treated the previous year is required due to tetraconazole's persistence and concerns for carryover to the following growing season.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2012-29, *Tetraconazole Technical Fungicide* are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/publi-regist/index-eng.php#rrd) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act*.